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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,602	08/23/2004	Annie McGee		8341

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Annie McGee
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EXAMINER

ROBERTS, LEZAH

ART UNIT PAPER NUMBER

1614

DATE MAILED: 11/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/784,602	Applicant(s) MCGEE, ANNIE	
	Examiner Lezah W. Roberts	Art Unit 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Note to Applicant:

An examination of this application reveals that applicant is unfamiliar with patent prosecution procedure. While an inventor may prosecute the application, lack of skill in this field usually acts as a liability in affording the maximum protection for the invention disclosed. Applicant is advised to secure the services of a registered patent attorney or agent to prosecute the application, since the value of a patent is largely dependent upon skilled preparation and prosecution. The Office cannot aid in selecting an attorney or agent.

A listing of registered patent attorneys and agents is available on the USPTO Internet web site <http://www.uspto.gov> in the Site Index under "Attorney and Agent Roster." Applicants may also obtain a list of registered patent attorneys and agents located in their area by writing to the Mail Stop OED, Director of the U. S. Patent and Trademark Office, PO Box 1450, Alexandria, VA 22313-1450

Applicant should submit an argument under the heading "Remarks" pointing out disagreements with the examiner's contentions. Applicant must also discuss the references applied against the claims, explaining how the claims avoid the references or distinguish from them.

Specification

The following is made to aid Applicant in the prosecution of the instant patent application.

Content of Specification

- (a) Title of the Invention: See 37 CFR 1.72(a) and MPEP § 606. The title of the invention should be placed at the top of the first page of the specification unless the title is provided in an application data sheet. The title of the invention should be brief but technically accurate and descriptive, preferably from two to seven words may not contain more than 500 characters.
- (b) Cross-References to Related Applications: See 37 CFR 1.78 and MPEP § 201.11.
- (f) Background of the Invention: See MPEP § 608.01(c). The specification should set forth the Background of the Invention in two parts:
 - (1) Field of the Invention: A statement of the field of art to which the invention pertains. This statement may include a paraphrasing of the applicable U.S. patent classification definitions of the subject matter of the claimed invention. This item may also be titled "Technical Field."
 - (2) Description of the Related Art including information disclosed under 37 CFR 1.97 and 37 CFR 1.98: A description of the related art known to the applicant and including, if applicable, references to specific related art and problems involved in the prior art which are solved by the applicant's invention. This item may also be titled "Background Art."
- (g) Brief Summary of the Invention: See MPEP § 608.01(d). A brief summary or general statement of the invention as set forth in 37 CFR 1.73. The summary is separate and distinct from the abstract and is directed toward the invention rather than the disclosure as a whole. The summary may point out the advantages of the invention or how it solves problems previously existent in the prior art (and preferably indicated in the Background of the Invention). In chemical cases it should point out in

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general terms the utility of the invention. If possible, the nature and gist of the invention or the inventive concept should be set forth. Objects of the invention should be treated briefly and only to the extent that they contribute to an understanding of the invention.

- (h) Brief Description of the Several Views of the Drawing(s): See MPEP § 608.01(f). A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74.
- (i) Detailed Description of the Invention: See MPEP § 608.01(g). A description of the preferred embodiment(s) of the invention as required in 37 CFR 1.71. The description should be as short and specific as is necessary to describe the invention adequately and accurately. Where elements or groups of elements, compounds, and processes, which are conventional and generally widely known in the field of the invention described and their exact nature or type is not necessary for an understanding and use of the invention by a person skilled in the art, they should not be described in detail. However, where particularly complicated subject matter is involved or where the elements, compounds, or processes may not be commonly or widely known in the field, the specification should refer to another patent or readily available publication which adequately describes the subject matter.
- (j) Claim or Claims: See 37 CFR 1.75 and MPEP § 608.01(m). The claim or claims must commence on separate sheet or electronic page (37 CFR 1.52(b)(3)). Where a claim sets forth a plurality of elements or steps, each element or step of the claim should be separated by a line indentation. There may be plural indentations to further segregate subcombinations or related steps. See 37 CFR 1.75 and MPEP § 608.01(i)-(p).
- (k) Abstract of the Disclosure: See MPEP § 608.01(f). A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims. In an international application which has entered the national stage (37 CFR 1.491(b)), the applicant need not submit an abstract commencing on a separate sheet if an abstract was published with the international application under PCT Article 21. The abstract that appears on the cover page of the pamphlet published by the International Bureau (IB) of the World Intellectual Property Organization (WIPO) is the abstract that will be used by the USPTO. See MPEP § 1893.03(e).

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Specification – New Matter

The amendment filed August 23, 2004 is objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure. 35 U.S.C. 132(a) states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: Applicant adds an additional ingredient, lemon rinds, to the mouthwash that was not in the originally disclosed specification. Also disclosed is a time limit for gargling. Applicant also removes matter from the specification such as the characteristics of the mouthwash.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claims

Claim Rejections - 35 USC § 112 – Scope of Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing or treating plaque, does not reasonably provide enablement for preventing plaque. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Attention is directed to In re Wands, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure

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would have required undue experimentation. Citing Ex parte Forman, 230 USPQ 546

(BdApls 1986) at 547 the court recited eight factors:

- 1) the nature of the invention,
- 2) the breadth of the claims
- 3) the relative skill of those in the art,
- 4) the state of the prior art,
- 5) the predictability of the art,
- 6) the amount of direction or guidance provided,
- 7) the presence or absence of working examples, and
- 8) the quantity of experimentation necessary,

The instant specification fails to provide guidance that would allow the skilled artisan to practice the instant invention without resorting to undue experimentation, as discussed in the subsections set forth infra.

The nature of the invention. The invention discloses using a composition comprising apple cider vinegar as a mouthwash.

The Breadth of the claims. The claims are broad because they read on "preventing".

Relative Skill of Those in the Art. The relative skill of those in the art are MS, MD D.D.S. and PhDs.

The State of the Prior Art. The prior art discloses that apple cider vinegar can be used to treat sore throats and improve the condition of the teeth, but makes no mention of its prophylactic ability to stop plaque from occurring. The term "preventing", moreover, is inclusive of prevention of plaque.

The Predictability or Lack Thereof in the Art. Prevention is not practical with oral dental plaque. Some people are more susceptible to plaque than others. According to

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the American Dental Association, plaque, a sticky film of bacteria, constantly forms on your teeth. When you eat or drink foods containing sugars or starches, the bacteria in plaque produce acids that attack the tooth enamel. The stickiness of the plaque keeps acids in contact with the teeth. It is also hard to prevent plaque because plaque is difficult to see without staining (Plaque: what it is and how to get rid of it). If plaque is constantly forming on the teeth and difficult to see, prevention is unlikely.

The Amount of Direction or Guidance Present. The disclosure does not appear to provide guidance for preventing plaque. It discloses how to make the mouthwash and its properties.

The Presence or Absence of Working Examples. There are no working examples in the disclosure.

The Quantity of Experimentation Necessary. The applicant needs to provide examples of using the mouthwash comprising the apple cider vinegar and water showing that plaque does not form and that the plaque was did not form due to the apple cider vinegar and water.

Suggested language: replace the term "preventing" with "inhibiting".

Claim Rejections - 35 USC § 112 - Indefiniteness

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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1) Claim 1 is rejected as failing to define the invention in the manner required by 35 U.S.C. 112, second paragraph.

The claim(s) are narrative in form and replete with indefinite and functional or operational language. The structure which goes to make up the device must be clearly and positively specified. The structure must be organized and correlated in such a manner as to present a complete operative device. The claim(s) must be in one sentence form only. Note the format of the claims in the patent(s) cited.

Applicant uses multiple sentences in the claims. The claim consists of five sentences and should be amended into one sentence.

Suggestion: The claim may read "1. A mouthwash for... comprising..." Please see US 5,376,374 for an example of the proper format for a claim.

2) Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) In claim 1, Applicant uses the phrase "includes no chemicals" in the first line of the claim. All the ingredients comprised in the disclosed mouthwash are "chemicals", even water. A chemical is defined as "1: of, relating to, used in, or produced by chemistry or the phenomena of chemistry (chemical reactions), 2: acting or operated or

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produced by chemicals". Acetic acid is a component of vinegar and is a chemical. It is suggested Applicant uses another phrase to describe the absence of

B) Claim 1 uses the term "heavenly" in the first line of the claim. The term heavenly is indefinite because it is defined as "1. Sublime; delightful; enchanting, 2. Of or relating to the firmament; celestial: *the sun, the moon, and other heavenly bodies*. Or 3. Of or relating to the abode of God; divine". The specification does not define exactly what is meant by "heavenly". The claim could be interpreted as a mouthwash made using the sun, the moon or other heavenly bodies. This makes the claim indefinite.

C) Claim 1 uses the term "natural" in the first line of the claim. It is not clear what is meant by "natural". It cannot be determined if a product found in nature and the same product synthesized in a laboratory is natural in both cases. This makes the term indefinite.

Claim Rejections - 35 USC § 101 - Utility

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 because it appears to be impossible to make because it is a "heavenly mouthwash". By the definition of heavenly the mouthwash is made from the sun, moon, other heavenly bodies, or in the abode of God.

Claim Rejections - 35 USC § 102 - Anticipation

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1) Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by
lacetoleather.com (<http://www.lacetoleather.com/wondrugpag4.html>).

The reference discloses apple cider vinegar in water as a mouthwash can be used to treat sore throats and to improve the condition of the teeth. The mouthwash can treat tooth decay, sore gums, ulcerated gums and whiten teeth. The reference anticipates the instant claims insofar as it discloses a mouthwash, which is an all “natural” product. The reference anticipates the instant claims insofar as it discloses an all “natural” mouthwash.

2) Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Newbury
Naturals Inc. (<http://web.archive.org/web/20030211112207/http://www.health911.com>).

Newbury Naturals Inc. disclose apple cider vinegar can be used as a mouthwash to rid of sore throats. The acidity should kill the bacteria on contact. Mix one teaspoon to 2 tablespoons in a glass of water. You can mix it as strong as you can stand it. The reference anticipates the instant claims insofar as it discloses an all “natural” mouthwash.

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3) Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Zelaya (US 5,376,374).

Zelaya discloses mouthwash compositions comprising vinegar. The preferred vinegar is apple cider vinegar. The mouthwash also comprises water where in the vinegar to water ratio ranges from 2:5 to 5:2 (col. 4, lines 40-50). The reference anticipates the instant claims insofar as it discloses an all "natural" mouthwash.

Claim 1 is rejected.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lezah W. Roberts whose telephone number is 571-272-1071. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lezah Roberts
Patent Examiner
Art Unit 1614



Frederick Krass
Primary Examiner
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